Disclaimer

Publication "Example Safety Assessment of an Impregnation Spray"

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Example Safety Assessment of an Impregnation Spray

Introduction

The »Recommendation for the safety assessment of detergents, maintenance and cleaning products« (1) gives a general description of the steps to be observed in the development and marketing of safe products of these types. The present publication highlights essential points of a safety assessment, by way of example, for the product group of impregnation sprays for leather and textiles. This publication was compiled by the IKW expert committee »Cleaning and Maintenance Products«, which consists of experts from competing companies. The neutrality of the committee is thus ensured.

Product Type Impregnation Sprays: General Description and Use

Impregnation sprays are preparations which predominantly contain fluorocarbon resins and/or silicones as active substances. They are offered as aerosols with or without propellant. Solvents used in these preparations are benzines or alcohols or mixtures of both. Impregnation sprays are used to provide protection against moisture and dirt; they are mainly applied onto shoes and items of clothing. They unfold their effect after suitable drying time.

Example Formulation, Classification of Raw Materials and Further Details

<table>
<thead>
<tr>
<th>Contents</th>
<th>Ingredient and classification according to the Dangerous Substances Directive (2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1%</td>
<td>Fluorocarbon resins; not classified as dangerous</td>
</tr>
<tr>
<td>0.5%</td>
<td>Silicone oils; not classified as dangerous</td>
</tr>
<tr>
<td>45%</td>
<td>Aliphatic hydrocarbons; R11, R38, R51/53, R65, R67</td>
</tr>
<tr>
<td>15%</td>
<td>Isopropanol; R11, R36, R67</td>
</tr>
<tr>
<td>5%</td>
<td>n-Butyl acetate; R10, R66, R67</td>
</tr>
<tr>
<td>100%</td>
<td>Propellant propane/butane; R12</td>
</tr>
</tbody>
</table>

Classification of the finished product, calculated according to the Preparations Directive (3): R12, R38, R51/53, R67

Notes:

It is important to ascertain that the safety data sheets of raw materials do not advise against use in spray products. If the raw materials are already registered under the REACh Regulation (4) and if a chemical safety report has been elaborated, exposure scenarios need to be attached to the safety data sheets. For each raw material, use in a spray product needs to be covered by an exposure scenario; where necessary, the formulator of the impregnation spray needs to follow the recommended risk reduction measures, in order to adequately control risks. If use in spray products is not included in the safety data sheets of raw materials, the manufacturer of the impregnation spray needs to become active according to Article 37 (4).
### Example Safety Assessment

<table>
<thead>
<tr>
<th>Step</th>
<th>Entry in the dossier; comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Selection of raw materials</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Not suitable based on general experiences:</strong></td>
<td></td>
</tr>
<tr>
<td>Reactive components</td>
<td></td>
</tr>
<tr>
<td>Film formers with high retention to the substrate (&gt; 90% retention on cotton-polyester [30/70] after one single wash (5))</td>
<td></td>
</tr>
<tr>
<td>Metal alcoholates, methylol compounds</td>
<td></td>
</tr>
<tr>
<td>Fragrances</td>
<td></td>
</tr>
<tr>
<td>Substances for which no experience is available in use in pressurized gas packaging</td>
<td></td>
</tr>
</tbody>
</table>

| **Assessment of input raw materials** | |
| **Plausibility check of safety data sheets** | »The toxicological and physical-chemical information in the safety data sheets is plausible«. |
| Information on constituents/components of the raw materials which are not stated in the safety data sheets of the raw materials. | Stating of all constituents / components of the raw materials which are relevant to classification (prescribed, but not always available). |
| These items of information are obtained e.g. by way of the following enquiries: | Stating of constituents with special structures, e.g. nanoparticles. |
| »Please let us have all the items of information which are necessary for the formulating of a spray product and its classification«. | Check for exclusion criteria. |
| These extra items of information ensure avoidance of additional risks. | |
| **Further relevant data:** | No substances are present which are banned or restricted under the REACH Regulation or under the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung) |

| **Assessment of the preparation** | |
| **Description of classification and labelling of the preparation** | |
| • Flammability: The use of propane/butane as propellant results in classification as extremely flammable with R12. | |
| • Acute toxicity: According to the calculation method of the Preparations Directive, this preparation is not classified as dangerous to health – based on the classifications of its ingredients (6). | |
| • Irritant effect on skin: According to the calculation method of the Preparations Directive, this preparation is classified as irritating to skin with R38 – based on the classifications of its ingredients. | |
| • Irritant effect on eyes: According to the calculation method of the Preparations Directive, this preparation is not classified as irritant to eyes – based on the classifications of its ingredients. | |
| • Sensitising ingredients: This preparation does not contain any ingredients in a percentage share of >0.1% which are classified as sensitising. | |
### Ecotoxicity:
According to the calculation method of the Preparations Directive, this preparation is classified as toxic to the aquatic environment with R51/53 – based on the classifications of its ingredients.

### Description of intended use:
Application according to the respective instructions for use and taking into account the specific warning (7).

### Assessment of impacts on human health
Impacts on human health are assessed stepwise, taking into account the items of information on the following points:

1. Results of the calculation method (see above)
   - The product is classified and labelled according to the Preparations Directive (see above).
2. Further necessary data for ingredients
   - The active constituents are not classified as toxic by inhalation.
3. Extra safety of the preparation as regards toxicity by inhalation (8)
   - Test conditions chosen for the test – in respect of concentration and exposure duration – constitute extremes, which will not occur in the intended use and when observing the warnings. Therefore slight, reversible impairments – which might be observed in the test – do not need to be expected in practice.
   - Note: If the result of the extra safety test for toxicity by inhalation shows that irreversible impairments or mortalities are observed, the formulation is not eligible for placing on the market.
4. Accompanying measures to limit the particle size spectrum (9)
   - Optimization of internal pressure through the share of propellant
   - Optimization of the primary particle size spectrum through the valve-spray nozzle-combination
   - Selection of solvents of medium vapour pressure, e.g. between 45 and 3 mbar at 20 °C
   - Also with the expected aging of the spray mist, the concentration of respirable particles is outside the critical range (10).

### Note for foam sprays:
In order to avoid high exposure of consumers using foam sprays, the following measures should be taken:

- A so-called foam head needs to be used. The foam head dispenses the content as foam which can be placed directly onto a cloth and distributed.
- The share of propellants, referred to the total formulation, should not be selected to be too high, e.g. max. 15%.

5. Irritant effect on skin
   - In the intended use, dermal contact is expected to be only short and at low concentration.
### Step

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<tr>
<td>6. Oral exposure</td>
<td>6. The input aliphatic hydrocarbons are labelled with risk phrase R65; however, according to Directive 67/548/EEC Annex VI 8.4, this does not apply in the following cases: «Substances classified as harmful on the basis of an aspiration hazard need not be labelled as harmful with R65 when placed on the market in aerosol containers or in containers fitted with a sealed spray attachment.»</td>
</tr>
</tbody>
</table>

### Impacts on the environment:

| Impacts on the environment: | Labelling with the symbol «dangerous to the environment» refers to the aliphatic hydrocarbons contained in the product, which constitute a danger to aquatic organisms. However, with the aerosol container the risk of solvents being released into waters is very low. Consequently, in the intended use there is no risk of damage to the aquatic environment. Solvents evaporate after use of the product. Like the propellant, they are degraded in the atmosphere within a few days. |

### Additional criteria:

<table>
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<tr>
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</tr>
</thead>
<tbody>
<tr>
<td>• Storage stability of the preparation (testing at -5 °C, +50 °C)</td>
</tr>
<tr>
<td>• Packaging</td>
</tr>
<tr>
<td>• The packaging fulfils the requirements of the Aerosol Directive and is labelled accordingly (11).</td>
</tr>
<tr>
<td>• Child-resistant fastening and tactile warning of danger according to the Preparations Directive are not necessary.</td>
</tr>
</tbody>
</table>

### Transport classification

| Transport classification | Class 2, item 5F, UN1950, aerosols |

### Labelling

<table>
<thead>
<tr>
<th>Labelling</th>
<th>Labelling according to the Preparations Directive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely flammable. Irritant to skin. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Vapours may cause drowsiness and dizziness. Do not breathe vapour/aerosol. Use only in well-ventilated areas. If swallowed, seek medical advice immediately and show this container or label. Do not empty into drains, dispose of this material and its container at hazardous or special waste collection point.</td>
<td></td>
</tr>
</tbody>
</table>

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Additional labelling according to the German Prepackages Ordinance (Fertigpackungsverordnung)
200 ml 3 e [270]

Additional labelling according to the German Chemicals Ban Ordinance (Chemikalienverbotsverordnung)
not necessary

Additional labelling according to the German Commodities Ordinance (Bedarfsgegenständeverordnung)
Vorsicht! Unbedingt beachten! Gesundheitsschäden durch Einatmen möglich! Nur im Freien oder bei guter Belüftung verwenden! Nur wenige Sekunden sprühen! Großflächige Textil- und Ledererzeugnisse nur im Freien besprühen und gut ablüften lassen! Von Kindern fernhalten!

(Free translation of labelling items – only for the purpose of this translation: «Caution! It is essential to observe these warnings! Inhalation can cause damage to health! Use only outdoors or in well-ventilated areas! Spray only for a few seconds! For large textile and leather products: spray only outdoors onto these products and allow to evaporate thoroughly! Keep out of reach of children!»)
Note:
The results of this safety assessment are included in quality assurance within the finished product (determined ingredients, conditions of filling). Adequate quality assurance measures ensure that the requirements derived from this safety assessment are complied with in production.

References:
(5) For example, hot wash/coloured laundry programme of a standard household washing machine at 40°C, using a heavy-duty detergent with bleaching agent on oxygen basis, drying in a tumble dryer at max. 65°C for 45 ± 5 minutes
(6) See »Assessment of impacts on human health«
(7) Labelling according to § 9 in conjunction with annex 7 of the German Commodities Ordinance (Bedarfsgegenständeverordnung) of 23 December 1997 (BGBl. I, 1998, p. 5), last amended by the 17th amending ordinance of 23.9.2009 (BGBl. I p. 3130)
(9) For example, SEHSC Guidance for aerosol application of silicon based materials (http://www.sehsc.com)

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